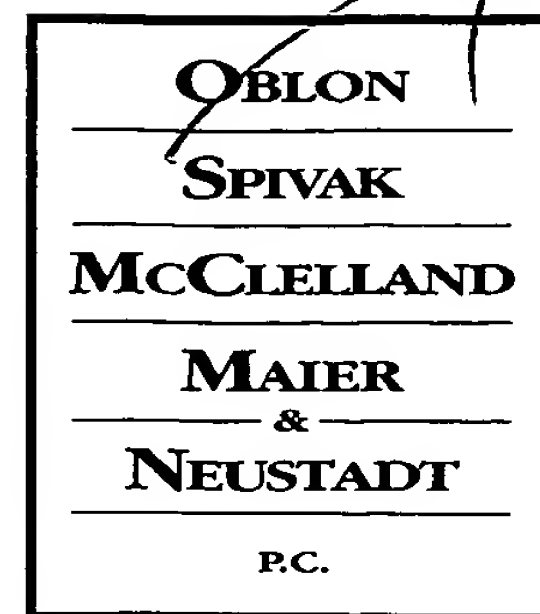


IFW

AF/1712

Docket No.: 0583-0252-0 FWC DIV

COMMISSIONER FOR PATENTS
ALEXANDRIA, VIRGINIA 22313



ATTORNEYS AT LAW

RE: Application Serial No.: 08/813,950
Applicants: Manfred ASSMUS, et al.
Filing Date: March 3, 1997
For: THERMOPLASTIC COATING AND BINDING
AGENT FOR MEDICINAL FORMS
Group Art Unit: 1712
Examiner: Sellers, R.

SIR:

Attached hereto for filing are the following papers:

Request for Oral Hearing; Reply Brief (In Triplicate)

Our credit card payment form in the amount of \$290.00 is attached covering any required fees. In the event any variance exists between the amount enclosed and the Patent Office charges for filing the above-noted documents, including any fees required under 37 C.F.R. 1.136 for any necessary Extension of Time to make the filing of the attached documents timely, please charge or credit the difference to our Deposit Account No. 15-0030. Further, if these papers are not considered timely filed, then a petition is hereby made under 37 C.F.R. 1.136 for the necessary extension of time. A duplicate copy of this sheet is enclosed.

Respectfully submitted,

OBLON, SPIVAK, McCLELLAND,
MAIER & NEUSTADT, P.C.
Norman F. Oblon

Harris A. Pitlick

Registration No. 38,779

Customer Number

22850

(703) 413-3000 (phone)
(703) 413-2220 (fax)

Docket No. 0583-0252-0 FWC DIV

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

IN RE APPLICATION OF: Manfred ASSMUS, et al.

SERIAL NO: 08/813,950

GAU: 1712

FILED: March 3, 1997

EXAMINER: Sellers, R.

FOR: THERMOPLASTIC COATING AND BINDING AGENT FOR MEDICINAL FORMS

REQUEST FOR ORAL HEARING

COMMISSIONER FOR PATENTS
ALEXANDRIA, VIRGINIA 22313

SIR:

Applicant's representative hereby respectfully requests that an Oral Hearing be scheduled in the above-identified application.

A credit card payment in the amount of \$290.00 to cover the fee is enclosed herewith and any further charges may be made against the Attorney of Record's Deposit Account No. 15-0030. A duplicate copy of this sheet is enclosed.

Respectfully Submitted,

OBLON, SPIVAK, McCLELLAND,
MAIER & NEUSTADT, P.C.
Norman F. Oblon


Harris A. Pitlick

Registration No. 38,779

Customer Number

22850

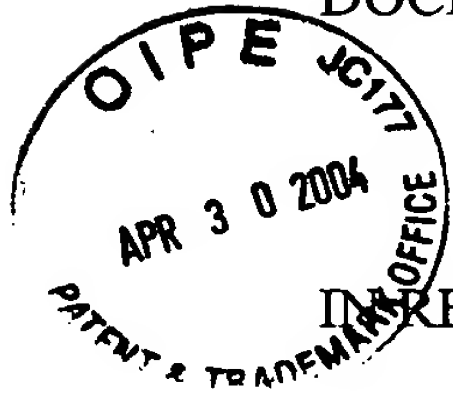
Tel. (703) 413-3000
Fax. (703) 413-2220
(OSMMN 05/03)

05/03/2004 CCHAUI 00000066 08813950

01 FC:1203

290.00 OP

DOCKET NO: 0583-0252-0 FWC DIV



IN THE UNITED STATES PATENT & TRADEMARK OFFICE

IN RE APPLICATION OF :

MANFRED ASSMUS, ET AL. :

EXAMINER: SELLERS, R.

SERIAL NO: 08/813,950 :

FILED: MARCH 3, 1997 :

GROUP ART UNIT: 1712

FOR: THERMOPLASTIC COATING AND :
BINDING AGENT FOR MEDICINAL
FORMS

REPLY BRIEF

COMMISSIONER FOR PATENTS
ALEXANDRIA, VIRGINIA 22313

SIR:

The following is in reply to the Examiner's Answer entered April 16, 2004 (Answer).

Appellants respectfully disagree with the Examiner's characterization of the difference between the presently-claimed subject matter and the subject matter before the Board in Appeal No. 2000-1405, as stated in Section (2) of the Answer. Suffice it to say that the presently-claimed subject matter is substantially narrower than the subject matter of the prior appeal, and the applied prior art, except for Mueller et al, is different from that relied on in the prior appeal.

The Examiner's statement of the rejection, in ¶¶ 1-37, has been rebutted in the Appeal Brief. The remainder of this Reply Brief is in rebuttal to the response to arguments of Section (11), beginning with ¶ 38, to the extent the Appeal Brief does not already rebut the arguments made in this Section.

Regarding the Examiner's findings on the first Assmus Declaration (§§ 38-41), the Examiner's findings that it does not show data for the presently-recited temperature range of 100-150°C, and fails to compare with what the Examiner characterizes as the "closest prior art with respect to the product-by-process hot-melt liquid application [which] is Yajima et al" (§ 39) were discussed and rebutted at page 5 of the Appeal Brief, which the Examiner has not addressed in the Answer. Moreover, there has never been an issue regarding the effectiveness of the present invention at the recited temperature range of 100-150°C. The purpose of the first Assmus Declaration was to demonstrate ineffectiveness at lower temperatures.

Regarding the finding that the first Assmus Declaration is not commensurate in scope with the claims since the scope of thermoplastic acrylic plastic (A) of the appealed claims is broader than the particular plastic exemplified in the first Assmus Declaration (§ 40) and that the numerical ratings "could be a function of the evaluator. Such ratings are not empirically sound and cannot be scientifically verified in the absence of more objective means of determining homogeneity such as microphotographs" (§ 41), the Examiner has never explained why one skilled in the art would not accept the results for the particular thermoplastic acrylic plastic (A) exemplified, in view of the fact that the claims require that the glass transition temperature of the mixture be no more than 20°K below the glass transition temperature of component A. Moreover, no findings have ever been made on this record with regard to the numerical ratings in the first Assmus Declaration. It is manifestly unfair for such a finding to be made for the first time at this point in the prosecution, depriving Appellants of the ability to point out why these ratings would be accepted by persons skilled in the art. The Board is respectfully requested to ignore this finding.

Regarding the Examiner's findings on the supplemental first Assmus Declaration (§§ 42-51), Appellants admit that data therein for other than GMS is not germane to the present

appeal, nor is the data for GMS (80%) germane. The relevant data therein concerns the characterization of the polymer particles for GMS (50%) at the three exemplified temperatures, thus providing further evidence of the significance of the minimum temperature of the 100° - 150°C range of the present claims.

The Examiner now, for the first time on this record, criticizes the meaning of the results (¶ 47). Thus, the Board should ignore this finding, as it should ignore the finding in ¶ 41, *supra*. The arguments made above with regard to the Examiner's findings on the first Assmus Declaration otherwise apply herein with regard to the supplemental first Assmus Declaration.

The Examiner finds that there is no evidence of record comparing products made by the presently-recited process compared to other processes, such as those disclosed by the applied prior art (¶ 51).

In reply, the process compared to in the above-discussed Assmus Declarations is closer than the so-called other processes, because the only difference in the comparative process is the lower temperature. Nevertheless, none of the applied prior art describes the product herein claimed. Thus, Appellants are under no burden to make such a comparison.

Regarding the Examiner's findings on the rejection over Petereit et al (¶¶ 52-54), there is simply no basis for finding that the 25-50% disclosure of tableting excipients and other components would be construed to mean that GMS could be the only excipient, or be present in an amount as high as 25%, especially when all the examples therein that contain GMS, employ GMS in a substantially lower amount. See also the discussion in the Appeal Brief at pages 6-7.

Regarding the Examiner's findings on the rejection over Yajima et al (¶¶ 55-56), despite the Examiner's attempted manipulation of percentage ranges of respective components, there is no way one of ordinary skill in the art from reading Yajima et al would

arrive at a combination of functional polymer and substance having a low melting point therein, wherein the substance was present in an amount of 20-50 wt%, by weight of the combination.

Regarding the Examiner's findings on the rejection over Burguiere et al in view of Mueller et al (§§ 57-60), the Examiner still has not addressed Appellants' argument in the Appeal Brief that without the present disclosure in the guide, one skilled in the art would not have combined Burguiere et al and Mueller et al. Indeed, the Examiner has not even shown that microcapsules of any kind could or would be made by any hot-melt extrusion method. Moreover, Appellants have never suggested that they were the first to carry out a melt extrusion process at temperatures at least overlapping those of the presently-recited 100-150°C range. But Mueller et al does not recognize the significance of that range, as proven in the first Assmus Declaration and supplemental first Assmus Declaration, compared to the much broader range disclosed therein.

Regarding the Examiner's findings on the rejection over Staniforth et al in view of Mueller et al (§§ 61-63), the Examiner finds that GMS is disclosed in Staniforth et al as a compressibility augmenting agent, and in an amount as large as 20% by weight (column 13, lines 37-39), but this disclosure of amount is with regard to the amount of microcrystalline cellulose present (column 13, line 40), not with regard to the sustained release carrier therein. The Examiner has not addressed Appellants' argument with regard to the *Baird* decision. In order to meet the terms of the present claims, not only would one of ordinary skill in the art have to select present components A and B from the broad disclosure in Staniforth et al, but one would have to also use component B in an amount of 25-50 wt% based on the combination of A and B, and assure that the result met the glass transition temperature limitations of the claims.

Regarding the Examiner's findings on the rejection over JP '317, Rudnic et al, and Pöllinger et al in view of Petereit et al and Mueller et al (§§ 64-70), the full English translation of the text of JP '317, cited now by the Examiner, provides additional support for Appellants' traversal of this rejection. Indeed, the full text actually teaches away from the presently-claimed invention, since in the one example containing GMS and a thermoplastic acrylic plastic, the GMS is present in an amount of approximately 11.8% by weight of the total of the plastic and GMS (Embodiment Example 1). Nor is there any indication of the melting temperature, glass transition temperature, or melt viscosity of the exemplified plastic. Appellants continue to submit that this rejection is based on a selection of bits and pieces of the applied prior art that support the rejection, while ignoring other disclosure therein that does not support the rejection.

Regarding the Examiner's findings on the rejection over Mueller et al in view of Petereit et al and Burguiere et al (§§ 71-72), even though conventional pharmaceutical auxiliaries in Mueller et al are optional, the Examiner finds that it would have been obvious to use a plasticizer or wetting agent in an amount as high as 30% by weight in view of Petereit et al and Burguiere et al. However, no particular need for such components is disclosed in Mueller et al, even if they may be present. Nor is there any disclosure or suggestion that if present, a material such as GMS would be added in amounts that are recited in the present claims.

Regarding what appears to be the Examiner's overall findings with regard to all the rejections of record (§§ 73-76), none of the prior art, alone or in any combination, discloses or suggests GMS in a minimum amount of 25%, based on the combination of GMS and a particular thermoplastic acrylic plastic. While some of the thermoplastic acrylic plastic disclosed in the applied prior art overlap some of those exemplified herein, such as some of the Eudragit brand polymers, not all Eudragit brand polymers, when combined with GMS,

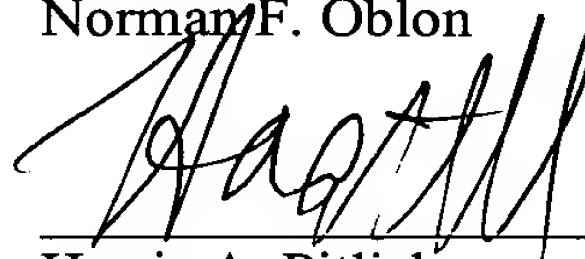
will necessarily result in the glass transition temperature of the mixture being no more than 20°K below the glass transition temperature of component A. Thus, in order to meet the terms of the present claims, it is not simply a matter of combining a polymer, even a Eudragit polymer, within the terms of component A, and combining it with GMS. To the extent that Appellants may not have shown any distinction between GMS and other flow improvers, or the presently-recited amount range of GMS compared to broader ranges, that is Appellants' discovery, not that of the prior art. Compare *In re Ruff*, 118 USPQ 340, 347 (CCPA 1958) ("To rely on an equivalence *known only to the applicant* to establish obviousness is to assume that his disclosure is a part of the prior art. The mere statement of this proposition reveals its fallaciousness.")

Since the applied prior art does not render the presently-claimed invention *prima facie* obvious, Appellants are under no duty to demonstrate such criticality or unexpected results. The above-discussed first Assmus Declaration and supplemental first Assmus Declaration, as evidence in support of patentability herein, must be considered herein, even though the present rejections must all be reversed even if this evidence were not in the case.

For all the above reasons, Appellants continue to maintain that all of the rejections of record should be REVERSED.

Respectfully submitted,

OBLON, SPIVAK, McCLELLAND,
MAIER & NEUSTADT, P.C.
Norman F. Oblon



Harris A. Pitlick
Registration No. 38,779

Customer Number
22850

Tel: (703) 413-3000
Fax: (703) 413 -2220
(OSMMN 08/03)
NFO/HAP/cja